

REMARKS

Claims 24-30 and 38-59 are pending in the instant application, with Claims 1-23, 31-37 and 60-69 canceled. A **Listing of Claims** with appropriate status identifier begins on page 2 of this communication.

By the present amendment, Claim 24 has been amended without prejudice or disclaimer of any previously claimed subject matter. Support for the amendment to Claim 24 can be found, *inter alia*, throughout the specification and the claims as originally filed. No new matter is introduced by the amendment. Specifically, Claim 24 has been amended to include the subject matter of Claims 26-28 and 56 with respect to the amylin agonist analogues contemplated therein. Claim 24 is further amended to define the invention with greater particularity with respect to the mammal in need of treatment according to the invention, support for which is found in the specification as originally filed at, e.g., page 46, lines 8-13.

The present amendment is made solely to promote prosecution without prejudice or disclaimer of any previously claimed subject matter. With respect to all amendments and canceled claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover, have not acquiesced to any rejections or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow. Applicants have carefully considered the points raised in the Office Action and believe that the Examiner's concerns have been addressed as described herein.

Rejection under 35 U.S.C. §102(b): Claims 24 and 38-40

The rejection of Claims 24 and 38-40 under 35 U.S.C. §102(b) (Office Action, page 3) for alleged anticipation over Sarantakis *et al.* (U.S. Pat. No. 4,451,394) is respectfully traversed.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also, MPEP §2131. The identical invention must be shown in complete detail as it is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913 (Fed. Cir. 1989). Applicants submit that the cited prior art fails to disclose each and every element of the present claims, and therefore does not anticipate the claimed invention.

Claim 24 as amended, and Claims 38-40 dependent therefrom, recite a method for reducing or moderating a postprandial rise in plasma glucose in a mammal, which method requires administering to the mammal an amylin agonist analogue selected from a defined genus of amylin agonist analogues having the sequence of SEQ ID NO:42, 44, 45 or 31. In contrast, Sarantakis *et al.* is silent with respect to amylin, amylin agonists, amylin agonist analogue, and in particular amylin agonist analogues with structure of SEQ ID NO:31, 42, 44 or 45.

Accordingly, Sarantakis *et al.* cannot anticipate Claims 24 and 38-30 because Sarantakis *et al.* does not disclose each and every element of the present claims. Thus, Applicants respectfully request reconsideration and withdrawal of the present rejection.

Rejection under 35 U.S.C. §112, first paragraph, written description: Claims 24 and 38-40

The rejection of Claims 24 and 38-40 under 35 U.S.C. §112, first paragraph (Office Action, page 6), as allegedly failing to comply with the written description requirement is respectfully traversed.

The proper standard for determining compliance with the written description requirement is whether the specification reasonably conveys to the skilled artisan that the inventor was in possession of the claimed invention as of the filing date. See MPEP § 2163.02 (citing *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 227 USPQ 177, 179 (Fed. Cir. 1985)). The subject matter of the claimed invention need not be described literally in the specification in order to satisfy the requirements of 35 U.S.C. § 112, first paragraph. *Id.* The written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of

species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus. See *Eli Lilly*, 119 F.3d at 1568, 43 USPQ2d at 1406.

The crux of the rejection, in the Examiner's words (Office Action, page 8, lines 8-12) appears to be that

[n]either the instant specification nor the claims have demonstrated common structure and/or function for the claimed genus of "amylin agonist analogues" that is a peptides and binds to a receptor, and can be used for treatment of lowering blood glucose. In addition, no representative numbers of species for each claimed genus is provided to show possession of the claimed genus of "amyloid agonist analogues."

Applicants respectfully submit that Claim 24 as amended contemplates a well defined genus of amylin agonist analogues having the structure of SEQ ID NO: 42, 44, 45 or 31, and that the specification provides numerous examples of specific peptides of the claimed genus (e.g., Examples A-Q). Thus, Applicants have met the burden regarding the disclosure of identifying (i.e., structural) characteristics of the claimed genus. Furthermore, the specification provides ample description of methods for testing the postprandial rise in blood glucose and the effect of amylin agonist analogues thereon (e.g., Examples 1-6). Accordingly, Applicants request reconsideration and withdrawal of the present rejection.

Rejection under 35 U.S.C. §112, second paragraph, enablement: Claims 24 and 38-40

The rejection of Claims 24 and 38-40 under 35 U.S.C. §112, second paragraph (Office Action, page 12), as allegedly failing to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the claimed invention commensurate in scope with the claims, is respectfully traversed.

Claim 24 as amended requires the use of an amylin agonist analogue having the structure of SEQ ID NO: 42, 44, 45 or 31, corresponding to elements a)-d), respectively, of the Markush definition of the genus of peptides provided in Claim 24.

As acknowledged by the Examiner (Office Action, page 12, lines 10-11), the specification is enabling for methods of treatment of reducing postprandial rise in blood glucose using peptides with SEQ ID NO: 1, 3, 6, 8-10, 31, 38 and 41-49. Thus, the claimed genus of peptides falls completely within the group of peptides acknowledged by the Examiner to be enabled. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

Rejection under 35 U.S.C. §112, second paragraph, indefiniteness: Claims 24-30 and 38-59.

The rejection of Claims 24-30 and 38-59 under 35 U.S.C. §112, second paragraph (Office Action, page 18), for alleged indefiniteness for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention, is respectfully traversed.

It is well established that when one skilled in the art would understand all of the language in the claims when read in light of the specification, a claim is not indefinite. *Rosemount Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1547, 221 USPQ 1, 7 (Fed. Cir. 1984), *Caterpillar Tractor Co. v. Bero*, S.P.A., 714 F.2d 1110, 1116, 219 USPQ 185, 188 (Fed. Cir. 1983).

Claim 24 as amended, and Claims 25-30 and 38-59 dependent therefrom, recite a method of reducing or moderating a postprandial rise in plasma glucose in a mammal, which method requires administering to the mammal an effective amount of an amylin agonist analogue having a defined sequence of SEQ ID NO: 42, 44, 45 or 31.

Applicants respectfully submit that the alleged indefiniteness of the terms "binds to an amylin receptor" and "binds" (Office Action, page 18, lines 8-10) is moot in view of the claim elements of Claim 24 as amended. Accordingly, Applicants respectfully request reconsideration and withdrawal of the present rejection.

CONCLUSION

Applicants believe that all issues raised in the Office Action have been properly addressed in this response. Accordingly, reconsideration and allowance of the pending claims are respectfully requested. If the Examiner believes that a telephone interview would serve to facilitate resolution of any outstanding issues, the Examiner is encouraged to contact Applicants' representative at the telephone number below.

No additional fees are believed due for this submission. However, if an additional fee is due, the Commissioner is hereby authorized to charge payment of any fees associated with this communication, to Applicant's Deposit Account No. 010535 referencing Docket No. 254/057CON. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Applicant's Deposit Account No. 010535.

Date: October 9, 2007

Respectfully submitted,

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